

Applicants : Robert L. Fine et al.
Serial No. : 10/587,606
Filed : November 13, 2006
Page 2 of 6 of October 30, 2008 Communication

REMARKS

Claims 1 to 20, 23, 26, 27, 28, 31, 36 and 37 are pending in the subject application. Applicants have not amended, added, or canceled any claims herein.

Election/Restrictions

On page 2, lines 3 to 17, of the September 30, 2008 Office Action the Examiner asserted that restriction to one of the following allegedly independent and distinct inventions is required under 35 U.S.C. §§ 121 and 372:

- I) claims 1 to 20, 23, and 26, drawn to a peptide comprising a first segment of SEQ ID NO:1 linked to a second segment having the sequence of SEQ ID NO:2 or a pharmaceutical composition comprising the peptide;
- II) claims 26 and 28, drawn to a DNA or viral vector encoding the peptide of SEQ ID NO:1 and 2;
- III) claim 31, drawn to an *in vivo* method of treating a subject suffering from cancer by administering to the subject the polypeptide; and
- IV) claim 37, drawn to an *in vitro* method of inducing apoptosis of a cell that contains mutant p53 or over-expressed wild type p53 comprising the cell with the peptide of claim 1.

The Examiner's specific rationale is set forth on page 2, line 17, to page 3, line 8, of the September 30, 2008 Office Action.

Applicants : Robert L. Fine et al.
Serial No. : 10/587,606
Filed : November 13, 2006
Page 3 of 6 of October 30, 2008 Communication

Applicants' Response

In response to the restriction requirement and solely in order to comply with 37 C.F.R. § 1.143, applicants hereby elect, with traverse, the invention identified by the Examiner as Group I, claims 1 to 20, 23, and 36. However, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement for at least the reasons that follow.

As an initial matter, applicants will address the Examiner's assertion at page 2, lines 21 to 25, of the September 30, 2008 Office Action. Specifically, the Examiner asserted that the claims of Group I, claims 1 to 20, 23, and 36, lack novelty or inventive step over U.S. Patent No. 5,527,676, issued June 18, 1996 to Bert Vogelstein et al. ("Vogelstein et al.").

The pending claims recite "[a] polypeptide comprising a first segment of continuous amino acids having the sequence AQAGKEPGGSRAHSSHLKSKKGQSTSRHKKLMFKTEGPDS (SEQ ID NO. 1) covalently linked to a second segment of continuous amino acids having the sequence DSDPGETKFMLKKHRSTSQGKKSKLHSSHARSGGPEKGAQA (SEQ ID NO. 2)" (emphasis added). Applicants note that SEQ ID NO:2 is a palindrome of SEQ ID NO:1. In other words, polypeptides of the pending claims require an element of a first segment of continuous amino acids having the sequence of SEQ ID NO:1 which is covalently linked to a separate element of a second segment of continuous amino acids having a sequence palindromic to SEQ ID NO:1.

The Examiner alleged that "Vogelstein et al. teach the amino acid sequence comprising the peptide of SEQ ID NO:1 or SEQ ID NO:2 that is a fragment of p53" at page 2, lines 23 to 25, of the September

Applicants : Robert L. Fine et al.
Serial No. : 10/587,606
Filed : November 13, 2006
Page 4 of 6 of October 30, 2008 Communication

30, 2008 Office Action. The Examiner asserted that this allegation is evidenced by the "sequence result" attached to the September 30, 2008 Office Action.

Applicants respectfully submit that Vogelstein et al. does not disclose a polypeptide with "a second segment of continuous amino acids having the sequence" of SEQ ID NO:2. Applicants respectfully submit that the Examiner has read the sequence listed on the "sequence result" in reverse order, i.e. from amino acids 393 to 353. Even if this is a valid interpretation of Vogelstein et al., which applicants deny, applicants respectfully submit that the Examiner has considered the same sequence twice, thereby combining two separate elements of the pending claims into one, to support the assertion that the claims of Group I lack novelty or inventive step over Vogelstein et al. Applicants respectfully submit that this "double counting" is clearly improper and overlooks the two separate elements of the pending claims, namely "a first segment of continuous amino acids" and "a second segment of continuous amino acids".

Turning now to the restriction requirement, applicants request that the Examiner reconsider and withdraw the restriction requirement as to Group I (claims 1 to 20, 23, and 36), Group II (claims 26 and 28), and Group III (claim 31) because the Examiner has not established a lack of unity of invention.

Specifically, the Examiner asserted that "[b]ecause the antibody for calreticulin is known in the art, the technical feature of Group II is not a special technical feature, the unity of invention (Groups I-III) is lacking" at page 3, lines 1 to 3, of the September 30, 2008 Office Action. Applicants note that none of claims 1 to 20, 23, and 36 (Group I), claims 26 and 28 (Group

Applicants : Robert L. Fine et al.
Serial No. : 10/587,606
Filed : November 13, 2006
Page 5 of 6 of October 30, 2008 Communication

II), and claim 31 (Group III), recite an "antibody for calreticulin". Applicants respectfully maintain that the Examiner has not established a lack of unity of invention.

Additionally, the Examiner asserted that "[t]he additional method of Group IV does not correspond to the main invention, as they are neither a method of making, nor a method of using said composition" at page 3, lines 4 to 5, of the September 30, 2008 Office Action. Applicants note that claim 37 recites "[a] method of inducing apoptosis of a cell that contains mutant p53 or over-expressed wild-type p53 comprising contacting the cell with the polypeptide of claim 1" (emphasis added). Applicants further note that claim 37 does not recite a "composition". Therefore, applicants respectfully maintain that the Examiner has not established a lack of unity of invention.

Further, under M.P.E.P. § 803 (8th Ed., 5th Rev., Aug. 2006), the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent or distinct, and (2) there must be a serious burden on the Examiner if restriction were not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required because a search of the prior art allegedly relevant to Group IV, *i.e.* claim 37, would not necessarily pose a serious burden once the prior art for Group III, *i.e.* claim 31, has been identified. Therefore, there is no burden on the Examiner to examine Groups I to IV together in the subject application.

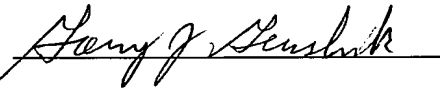
Applicants : Robert L. Fine et al.
Serial No. : 10/587,606
Filed : November 13, 2006
Page 6 of 6 of October 30, 2008 Communication

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §§ 121 and 372, and respectfully request that the Examiner reconsider and withdraw the requirement for restriction under 35 U.S.C. §§ 121 and 372.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.


Respectfully submitted,



John P. White
Registration No. 28,678
Gary J. Gershik
Registration No. 39,992
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Gary J. Gershik Date
Reg. No. 39,992